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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TRAVIS ITO-STONE, Individually and on behalf of all others similarly situated,

Plaintiff,

v.

DBV TECHNOLOGIES S.A., DANIEL TASSÉ, PIERRE-HENRI BENHAMOU, and DAVID SCHILANSKY, SUSANNA MESA

Defendants.

Case No. 2:19-cv-00525-MCA-LDW

AMENDED CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS

JURY TRIAL DEMANDED

CLASS ACTION

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Lead Plaintiffs Ruth Pruitt and Asdrubal Delgado ("Investors" or "Plaintiffs") individually and on behalf of all other persons similarly situated, by Investors' undersigned attorneys, for Investors' complaint against Defendants (defined below), alleges the following based upon personal knowledge as to Investors' and Investors' own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Investors' attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding DBV Technologies S.A. ("DBV" or the "Company"), investigative interviews with former employees of the Company, consultation with an expert on issues concerning FDA approval, and review of other publicly available information concerning DBV. Investors believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities, other than Defendants, who purchased publicly traded American Depository Shares ("ADS") of DBV on the NASDAQ during the period from February 14, 2018 through December 19, 2018, inclusive (the "Class

Period"). Investors seek to recover compensable damages caused by Defendants' violations of the federal securities laws under Section 10(b) and 20(a) the Securities Exchange Act of 1934 (the "Exchange Act").

2. DBV is a clinical-stage specialty biopharmaceutical company focused on changing the field of immunotherapy by developing a novel technology platform called Viaskin. DBV's lead product candidate is the Viaskin Peanut, a patch to be worn on the skin, designed to treat peanut allergies in children, adolescents and adults.

3. Defendants were in a race to market to become the first company to develop an United States Food and Drug Administration ("FDA") approved peanut allergy treatment, as there are no drugs or biologics on the market to treat peanut allergies.

4. The Viaskin Peanut patch must be approved by the FDA through the Biologics License Application ("BLA") process before it can be legally marketed and sold to the public.

5. On February 14, 2018, DBV announced that the FDA agreed that the available efficacy and safety data for Viaskin Peanut was sufficient to support the submission of a BLA.

6. The market responded exuberantly to DBV's long-awaited announcement that the FDA reacted favorably to safety and efficacy of the data as

supporting a BLA. After DBV's February 14, 2018 announcement the price of DBV's ADS traded at a whopping *nineteen times* the previous day's volume.

7. Thereafter throughout the Class Period, Defendants touted the Company's manufacturing process and assured investors that DBV was prepared to launch the Viaskin Peanut in 2019 based on its work "scaling up" and "refin[ing] our manufacturing process."

8. Unbeknownst to investors, however, DBV was experiencing serious problems with chemistry, manufacturing and controls ("CMC") and current good clinical practices ("cGMP") in connection with its electrospray technology. The electrospray manufacturing process, fully developed by DBV, was ***intended*** to spray homogenous, thin, dry protein layers onto the Viaskin patch. According to former employees of DBV, the electrospray technology had never been used by another company and there were intractable problems in scaling up such a technology for commercial production.

9. According to a former employee, DBV could not produce the Viaskin Peanut patch consistently and was having trouble controlling the exact 250mg dose that needed to be sprayed onto each Viaskin patch due to the spray-jets becoming clogged while running at full production. In other words, DBV was unable to consistently produce the Viaskin Peanut product at optimal production levels needed for commercial production, and for approval of a BLA.

10. Despite these issues, Defendants forged on, and leading up DBV's March 23, 2018 public offering – in which Defendants raised *$172.5 million* from investors – Defendants continued to tout Viaskin and its electrospray technology's readiness to support DBV's BLA. As stated by Defendant Mesa, DBV's Chief Business Officer, on March 14, 2018 at Barclay's Global Healthcare Conference:

> It's an electrostatic patch. We have our own machine in-house that we've developed in order to not only formulate the antigen that goes in to the patch, but you spray it in a very unique manner, which is what allows Viaskin to deliver the antigen in the skin and not through the bloodstream.
>
> So we also have, aside from the clinical standpoint, some CMC requirements that need to be filed with the BLA filing as well. ***So all of those items will be ready in the second half this year, and that keeps us on track in terms of when we expect to get clinical approval*** and if the products is approved and when we would launch if the product is indeed approved.

11. October 22, 2018, DBV announced it had submitted a BLA to the FDA for Viaskin Peanut. The submission of the BLA triggered a 60-day review period during which the FDA would preliminarily assess the BLA to determine whether the BLA would be accepted for a full review, or whether the FDA would issue a refusal to file ("RTF") the application.[1] Thus, the FDA's decision on the sufficiency of the BLA submission was due on December 21, 2018.

[1] An RTF is "refuse to file." When an NDA or BLA is deemed incomplete by the FDA it can decide not to review the application.

12. Surprisingly, shortly after DBV submitted its BLA for Viaskin Peanut—a product the Company had been working on for 10 years—on November 29, 2018, Defendant Pierre-Henri Benhamou, DBV's CEO and co-founder since 2002, resigned from the Company.

13. Following the submission of DBV's BLA, the Company continued to experience serious manufacturing complications threatening its BLA. As a result of these CMC problems, just days before the FDA's decision on whether it would accept the BLA for filing was to be issued, DBV withdrew the application to avoid receiving an RTF. On December 19, 2018, after the close of trading, the Company shocked investors when it issued a press release announcing that its "BLA [for Viaskin Peanut was] withdrawn following discussions with the FDA regarding ***insufficient data on manufacturing procedures and quality controls***[.]"

14. Given the Company's repeated assurances about the readiness of its manufacturing processes during the Class Period, the market was stunned by the announcement. Following this news, the Company's share price plummeted, dropping $8.39 per share, from a closing price of $14.15 on December 19, 2018 to close at $5.76 on December 20, 2018—a one-day drop of nearly 60%.

15. As a result of Defendants' misrepresentations about the adequacy of Viaskin Peanut's manufacturing process and quality controls, and the precipitous

decline in the market value of the Company's securities, Plaintiffs and other Class members have suffered significant losses and damages.

II. JURISDICTION AND VENUE

16. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

17. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, and Section 27 of the Exchange Act (15 U.S.C. §78aa).

18. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)) as the alleged misstatements entered and the subsequent damages took place in this judicial district, and the Company has operations and conducts substantial business in this district.

19. In connection with the acts, conduct and other wrongs alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications, and the facilities of the national securities exchange.

III. PARTIES

20. Lead Plaintiff Ruth Pruitt purchased DBV ADS at artificially inflated prices during the Class Period and has been damaged thereby. Her PSLRA certification was previously filed with this Court (Dkt. No. 5-5) and is incorporated by reference herein.

21. Lead Plaintiff Asdrubal Delgado purchased DBV ADS at artificially inflated prices during the Class Period and has been damaged thereby. His PSLRA certification was previously filed with this Court (Dkt. No. 5-5) and is incorporated by reference herein.

22. Defendant DBV was incorporated in France in 2002. DBV's principal executive offices are in Montrouge, France. DBV is a clinical-stage specialty biopharmaceutical company focused on changing the field of immunotherapy by developing a novel technology platform called Viaskin. DBV's lead product candidate is the Viaskin Peanut, designed to treat peanut allergies in children, adolescents and adults. DBV also has offices in North America in New York, New York and Summit, New Jersey. DBV's Summit New Jersey office is a commercial facility intended to support the launch and commercialization of Viaskin Peanut in North America if the appropriate regularly approvals are received. DBV ADS began trading on the NASDAQ Global Select Market ("NASDAQ") under the ticker symbol "DBVT" on October 22, 2014.

DBV's ordinary shares have traded on the Euronext Paris Stock Exchange under the symbol "DBV" since its initial public offering in March 2012.

23. Defendant Daniel Tassé ("Tassé") has served as the Company's Chief Executive Officer ("CEO") since November 29, 2018.

24. Defendant Pierre-Henri Benhamou ("Benhamou") co-founded DBV Technologies in 2002. Benhamou served as the Company's CEO from 2002 until November 29, 2018. Prior to co-founding DBV, Benhamou was a physician in pediatric gastroenterology.

25. Defendant David Schilanksy ("Schilanksy") has served as the Company's Deputy Chief Executive Officer (also known as the Principal Financial Officer) since December 2017. Schilansky served as the Company's Chief Operating Officer ("COO") from January 2015 until December 2017.

26. Defendant Susanna Mesa ("Mesa") has served as the Company's Chief Business Officer ("CBO") since December 2017. Prior to serving as the CBO, Mesa was the Company's Senior Vice President of Strategy from April 2016 to December 2017.

27. Defendants Tassé, Benhamou, Schilanksy, and Mesa are collectively referred to herein as the "Individual Defendants."

Each of the Individual Defendants:

(a) directly participated in the management of the Company;

(b) was directly involved in the day-to-day operations of the Company at the highest levels;

(c) was privy to confidential proprietary information concerning the Company and its business and operations;

(d) was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;

(e) was directly or indirectly involved in the oversight or implementation of the Company's internal controls;

(f) was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or

(g) approved or ratified these statements in violation of the federal securities laws.

28. DBV is liable for the acts of the Individual Defendants and its employees under the doctrine of *respondeat superior* and common law principles of agency because all of the wrongful acts complained of herein were carried out within the scope of their employment.

29. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to DBV under *respondeat superior* and agency principles.

30. Defendants DBV and the Individual Defendants are collectively referred to herein as "Defendants."

IV. BACKGROUND

A. Company Background and the Viaskin Peanut

31. As a clinical stage biopharmaceutical company, DBV has not generated income from its operating activities and has incurred net losses each year since its inception in 2002. DBV has devoted most of its financial resources to research and development, including clinical and pre-clinical development activities. DBV has primarily funded its operations through the sale of equity securities.

32. DBV's lead product candidate is a patch worn on the skin called the Viaskin Peanut patch, designed to treat peanut allergies. The patch is designed to deliver peanut allergens in a controlled manner to stimulate immune intolerance. For patients facing potentially life-threatening peanut allergies this treatment aims to desensitize them to allergens by delivering compounds in small quantities into the outer layers of the skin.

33. Indeed, there are currently no drugs or biologics on the market that treat peanut allergies. Treatment of peanut allergies is an important unmet need. According to a paper published in the Immunology and Allergy Clinics of North America, food allergies - mainly peanut allergies, are responsible for 150 to 200

deaths and about 200,000 emergency room visits every year in the United States. Peanut allergies are particularly difficult for young children to manage, and due to their life-threatening nature, can lead to psychological trauma and social anxiety. In some cases, these allergies can also cause chronic diseases such as failure to thrive in children and an allergic inflammatory condition of the esophagus called eosinophilic esophagitis, or EoE.

34. Given this critical unmet need—and major market opportunity—DBV was in a race to market to become the first company to develop an FDA approved peanut allergy treatment, competing against rival company Aimmune Therapeutics, Inc., which is also developing a peanut allergy treatment consisting of a formulation of peanut flour for oral administration intended for oral desensitization to peanut. The untapped market for peanut allergy treatment is expected to grow to $4.5 billion globally by 2027.

35. DBV describes itself as "focused on changing the field of immunotherapy by developing a novel technology platform called Viaskin." DBV's therapeutic approach is based on epicutaneous immunotherapy, or "EPIT," its proprietary method of delivering biologically active compounds to the immune system through intact skin using Viaskin. DBV's proprietary platform is its epicutaneous Viaskin patch. DBV designed and developed this technology internally, representing that it had "scalable manufacturing capabilities."

36. Viaskin is an electrostatic patch which DBV describes as offering a "convenient, self-administered, non-invasive immunotherapy to patients." The process, fully developed by DBV, uses an electrospray to spray homogenous, thin, dry protein layers onto the Viaskin patch. This process sprays a liquid solution of electrically charged proteins onto the patch's backing, which is then turned into a dry solid charged particle, which remains stuck into the patch's backing. It deposits very small and precise quantities of the active substance, devoid of adjuvants. The patch can then by stored at room temperature, providing a long shelf life. When Viaskin is applied on intact skin it forms a condensation chamber which hydrates the skin and solubilizes (dissolves) the antigen, allowing it to penetrate the epidermis, where it is captured by cells. This mechanism is designed to generate an immune response that results in allergen desensitization. Desensitization consists of repeated administration of small quantities of allergen to decrease allergen reactivity in patients.

37. DBV believes that EPIT is a preferred method of desensitization compared to other desensitization methods, such as subcutaneous, sublingual and oral immunotherapy, which often require frequent or prolonged administration in specialized centers. These methods are considered poorly designed for pediatric patients due to their safety profile and method of administration. Some of these approaches are also known for triggering severe adverse events related to

treatment, including anaphylaxis, risking the patient's life. Accordingly, DBV believes that Viaskin has positioned DBV as the company with the most advanced clinical program in food allergies to date.

B. The FDA Approval Process

38. In the United States the FDA regulates biologics under the Federal Food, Drug and Cosmetic Act, or FDCA.

39. The Viaskin Peanut patch must be approved by the FDA through the Biologics License Application, BLA, process before it can be legally marketed.

40. As DBV stated in its 2017 Form 20-F filed with the SEC on March 16, 2018 ("2017 20-F") the FDA process before a biologic can be marketed in the U.S. generally involves the following:

- completion of extensive nonclinical, sometimes referred to as pre-clinical laboratory tests, pre-clinical animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice, or GLP, regulations;

- submission to the FDA of an IND, which must become effective before human clinical trials may begin;

- performance of adequate and well-controlled human clinical trials in accordance with applicable IND and other clinical trial-related regulations, sometimes referred to as good clinical practices, or GCPs, to establish the safety and efficacy of the proposed product candidate for its proposed indication;

- submission to the FDA of a BLA;

- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the product is produced to assess

compliance with the FDA's current good manufacturing practice, or cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality, purity and potency;

- potential FDA audit of the pre-clinical and/or clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval of the BLA prior to any commercial marketing or sale of the product in the United States.

41. The data necessary to support a BLA is generated in two distinct stages: pre-clinical and clinical. The pre-clinical development stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The clinical stage of development involves the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators.

42. Clinical trials are generally conducted in three sequential phases that may overlap, known as Phase I, Phase II and Phase III clinical trials. Phase III clinical trials generally involve large numbers of patients at multiple sites, in multiple countries (from several hundred to several thousand subjects) and are designed to provide the data necessary to demonstrate the efficacy of the product for its intended use, its safety in use, and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval.

Generally, two adequate and well-controlled Phase III clinical trials are required by the FDA for approval of a BLA.

43. Following trial completion, trial data is analyzed to assess safety and efficacy. The results of pre-clinical studies and clinical trials are then submitted to the FDA as part of a BLA, along with proposed labeling for the product and information about the manufacturing process and facilities that will be used to ensure product quality, results of analytical testing conducted on the chemistry of the product candidate, and other relevant information.

44. The BLA is a request for approval to market the biologic for one or more specified indications and must contain proof of safety, purity, potency and efficacy, which is demonstrated by extensive pre-clinical and clinical testing.

45. After the BLA submission is accepted for filing, the FDA reviews the BLA to determine, among other things, whether the proposed product candidate is safe and effective for its intended use, and whether the product candidate is being manufactured in accordance with "Current Good Manufacturing Practice" or "cGMP" to assure and preserve the product candidate's identity, strength, quality, purity and potency.

46. Before approving a BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMPs. The FDA will not approve the

product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

47. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the BLA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal Phase III clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, pre-clinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

C. cGMP and CMC

48. Part 211 of Title 21 of the Code of Federal Regulations ("CFR") sets for Current Good Manufacturing Practice for Finished Pharmaceuticals (i.e. cGMP). Part 211 contains twelve subparts, A-K, each of which have various subsections. These detailed regulations alert manufactures as to the requirements

concerning: buildings and facilities, organization and personnel, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling control, holding and distribution, laboratory controls, records and reports and returned and salvaged drug products. In other words, GMPs cover all aspects of production- from the materials, premises and equipment to the qualifications, training and personal hygiene of staff and management. Detailed written procedures are essential for the quality of a finished product. A manufacturer must establish specific recordkeeping instructions demonstrating that procedures are consistently and correctly followed at each step in the manufacturing process, each time a product is made.[2]

49. The goals of cGMPs are to ensure that the marketed product is the same or similar to the product demonstrated to be safe and effective in the clinical safety and effectiveness studies; to ensure that the manufacturing process consistently yields a product meeting approved qualify attributes; and to ensure that the product will maintain its quality attributes throughout its shelf life. *Id.*

50. CMC refers to Chemistry, Manufacturing and Controls. CMC review and cGMP compliance may overlap but are not the same. GMPs relate to quality

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[2] *See* "Chemistry, Manufacturing and Controls (CMC) and Good Manufacturing Practices (GMPs): The Big Picture of a Long-term Commitment," Elizabeth Pollina Cormier, Ph.D., Review Chemist Division of Manufacturing Technologies FDA/CVM/ONADE, available at: www.accessdata.fda.gov>static>cvm>cormier>CMCsandCGMPS.

systems, overall operation and is facility oriented. CMC is product specific and relates to understanding process. *Id.* The critical elements of CMC look at: How and where the drug is made, how raw materials are tested and monitored, what control procedures are in place to assure product consistency and quality, whether quality attributes are adequately identified and characterized for the product, whether test methods to use product quality are appropriate and how long the product maintains its quality after it is made. *Id.*

51. CMC exists to assure that the drug sold to the public will have quality attributes similar to those of the drug demonstrated to be safe and effective; to assure that the quality of the drug meets appropriate standards and is consistent; and to assure that the drug is the same drug as described on the label. *Id.* In short, CMC helps maintain the connection in quality between the drug used in the clinical studies and the drug to be marketed to consumers. *Id*. For example, a manufacturing process under control will exhibit consistency of product quality with low variability between different batches of the product. *Id.*

52. The bottom line is that through ensuring CMC and cGMP compliance, manufacturers ensure that quality is designed into the manufacturing process itself and that quality is maintained as long as the product is marketed.

D. DBV has been Developing the Viaskin Peanut for over 10 years.

53. The Viaskin peanut received "Breakthrough" and "fast track designation" from the FDA in 2015 and 2012, respectively. A breakthrough therapy is defined as a product that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. A breakthrough therapy designation affords the possibility of rolling review, enabling the agency to review portions of the marketing application before submission of a complete application, and priority review if supported by clinical data at the time of our BLA submission. "Fast track" designation means a product may have a faster development process. A manufacturer can apply for "fast track" designation where the product is intended for the treatment of a serious or life-threatening condition and nonclinical or clinical data demonstrate the potential to address unmet medical needs for this condition.

54. In September 2014, DBV announced topline results for its Viaskin Peanut's Efficacy and Safety, or VIPES, Phase IIb clinical trial of Viaskin Peanut for the treatment of peanut allergic patients.

55. In October 2016, DBV announced topline results from the two-year OLFUS-VIPES study evaluating the long-term efficacy and safety profile of Viaskin Peanut for the treatment of peanut allergic children. OLFUS-VIPES, or OLFUS, is an open-label, follow-up study to VIPES.

56. Following results from the Phase IIb programs above, DBV launched a Phase III program designed to assess the efficacy and safety of Viaskin Peanut in children. As part of its Phase III program development, DBV initiated the Peanut EPIT Efficacy and Safety Study, or PEPITES, a pivotal Phase III trial, in December 2015. PEPITES was designed to evaluate the safety and efficacy of Viaskin Peanut 250 µg in 356 peanut allergic patients four to 11 years of age.

57. In August 2016, DBV launched the REAL Life Use and Safety of EPIT (REALISE) study, which was designed to evaluate the use and safety of Viaskin Peanut 250 µg in routine clinical practice in 393 peanut allergic patients four to 11 years of age.

58. In August 2017, DBV initiated the EPIT in Toddlers with Peanut Allergy, or EPITOPE, a Phase III clinical trial assessing the safety and efficacy of Viaskin Peanut for the treatment of peanut allergic patients one to three years of age.

59. In October 2017, DBV announced topline results from PEPITES, in which DBV observed a statistically significant response with a favorable

tolerability profile, with 35.3% of patients responding to Viaskin Peanut 250 µg after 12 months of treatment as compared to 13.6% of patients in the placebo arm (difference in response rates = 21.7%; p=0.00001; 95% CI = 12.4% - 29.8%). However, the primary endpoint, which evaluates the 95% confidence interval, or CI, in the difference in response rates between the active and placebo arms, did not reach the 15% lower bound of the CI that was proposed in the trial's Statistical Analysis Plan submitted to the FDA.

60. In November 2017, DBV announced topline safety results from REALISE and that the trial met its primary objective. In the trial, DBV observed that Viaskin Peanut was well-tolerated with no new or unexpected adverse events.

61. On February 14, 2018 DBV announced that the FDA agreed that the available efficacy and safety data for Viaskin Peanut supports the submission of a BLA, for the treatment of peanut allergy in children four to 11 years of age. The results from the PEPTITES and REALISE studies formed DBV's BLA submission to the FDA. The FDA provided written responses to the clinical pre-BLA meeting package DBV submitted. These responses reflect agreement on the content of the clinical module of the BLA for Viaskin Peanut.

V. DEFENDANTS MISLEAD INVESTORS CONCERNING DBV'S BLA FOR VIASKIN PEANUT

62. As noted above, in order to receive FDA approval, a biologic must not only be demonstrated to be safe and effective as proven through data from

clinical trials, manufacturing of the product must comport with cGMP and CMC. Indeed, throughout the Class Period Defendants acknowledged the importance of CMC and cGMP for a product like the Viaskin Peanut.

63. Unbeknownst to investors, however, prior to, and during the heart of the Class Period, DBV was experiencing CMC and cGMP problems with its electrospray technology. The electrospray manufacturing process, fully developed by DBV, was ***intended*** to spray homogenous, thin, dry protein layers onto the Viaskin patch. According to former DBV employees, the electrospray technology had never been used by another company and there were significant problems in scaling up the technology for commercial production, a necessity for DBV to obtain the FDA's approval of the BLA.

A. Confidential Witnesses Describe Serious Manufacturing and CMC Problems of Viaskin Peanut

64. Confidential Witness 1 ("CW1"), a Regional Director of Supply Chain from October 2016 to August 2017, traveled to DBV's manufacturing facility in France in the course of CW1's job duties. CW1 recalled that DBV was significantly behind in scaling up its Viaskin Peanut manufacturing operations to launch a commercial product. Based on what CW1 saw during this visit, CW1 said that although the Company had certain elements in place, such as financing, the Company had "a long way to go" in regard to scaling up the manufacturing processes.

65. CW1 stated that the Viaskin Peanut product represented "challenging" technology. As CW1 explained, the Viaskin Peanut product entailed atomizing a biologic agent into a substrate (*i.e.*, a liquid solution of electrically charged protein is sprayed onto the patch's backing, which turns into a dry solid charged particle). CW1 noted that the electrospray had the potential to be an "amazing" technology, but based on what CW1 saw during the visit to France, the technology was "not scaled up" for commercial production. In short, while DBV could produce small batches for the Phase 3 trials, the technology was inadequate to produce the large scale batches required for commercial production and FDA approval.

66. CW1 further reported that DBV was also experiencing a significant problem with the stability of the Viaskin Peanut patch. CW1 recalled that the Viaskin patches had been designed in such a way that it would fall off during the clinical trials. CW1 noted that this may have reflected a poor product design. According to CW1, a flat patch would have limited condensation between the under-layer of the patch and the skin, but the patch DBV was using at the time was ring-shaped, and it created condensation when the substrate and the peanut protein

went into action, resulting in the patch falling off of patients. Product stability is also required for FDA approval.[3]

67. Confidential Witness 2 ("CW2") worked at DBV Technologies as a Senior Director, Market Development (Food Allergies) from April 2016 to February 2018. Prior to CW2's employment with DBV, CW2 previously worked at a large pharmaceutical company, Sanofi, at which CW2 had the opportunity to observe its manufacturing processes and capabilities.

68. In the course of CW2's employment for DBV, CW2 visited the Company's manufacturing facility in France several times as part of CW2's efforts to develop educational materials regarding the allergies that Viaskin was intended to treat and how DBV's products worked and addressed those ailments. During the time periods of CW2's visits to the French manufacturing facility, DBV had been in the process of preparing its manufacturing for clinical batches of the Viaskin Peanut product. CW2 observed that DBV "didn't have experienced people" in charge of CMC and manufacturing of Viaskin Peanut. CW2 also observed that DBV's manufacturing processes and capabilities were "not as established" in relation to CW2's prior experience with Sanofi.

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[3] *See*, *e.g.*, FDA guidance: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q5c-quality-biotechnological-products-stability-testing-biotechnologicalbiological-products.

69. CW2 further relayed CW2's understanding that the technology DBV was seeking to employ to manufacture the Viaskin Peanut had never before been used to produce a commercial grade pharmaceutical product. CW2 said that DBV's website included information about how it uses an innovative "electro-spray" technology to spray the allergen onto the patch, but CW2 learned that there were problems scaling up and implementing the new technology.

70. Consistent with CW1's account, CW2 also reported learning of problems of the Viaskin Peanut patch failing to stay adhered to the skin during its clinical trials.

71. At the time of CW2's departure from DBV in February 2018, based on CW2's knowledge of DBV's development and manufacturing of Viaskin Peanut, and CW2's concerns relating to the same, CW2 did not believe that DBV realistically would be able to submit its BLA for Viaskin to the FDA and be successful "anytime soon." Still, CW2 explained, CW2 believed that DBV was in a race against its competitors and needed to show progress by submitting the BLA in 2018.

72. Confidential Witness 3 ("CW3") worked as an outside consultant for DBV from February 2019 through May 2019. In the course of CW3's work for DBV, CW3 learned that the reason the BLA for Viaskin Peanut was withdrawn in December 2018 was due to a quality control problem with the manufacturing

system that was used to spray the active ingredient onto the patches. More specifically, DBV could not produce the Viaskin Peanut patch consistently and was having trouble controlling the exact 250mg dose that needed to be sprayed onto each Viaskin patch due to the spray-jets becoming clogged while running at full production. In other words, DBV was unable to consistently produce the Viaskin Peanut product at optimal production levels required for commercial production and FDA approval.

73. Despite Defendants' knowledge of the CMC and cGMP problems with its electrospray technology during the Class Period – specifically, that the Company could not create reproducible and consistent Viaskin Peanut patches during production because the electrospray jets were becoming clogged – Defendants, leading up to DBV's March 2018 public offering, continued to mislead investors about the status of Viaskin's manufacturing readiness.

B. During the Class Period, and Particularly Leading up to Defendants' Public Offering, Defendants Misled Investors About the Status of Viaskin Peanut's CMC and Manufacturing Readiness

74. On February 14, 2018 the Company issued a press release entitled, "DBV Technologies Provides Update on Regulatory Progress for Viaskin Peanut," which stated the FDA agreed that the available efficacy and safety data for Viaskin Peanut supported the submission of a Biologics License Application ("BLA"). The press release stated, in relevant part:

> DBV Technologies Provides Update on Regulatory Progress for Viaskin Peanut
>
> DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT) today announced that the U.S. Food and Drug Administration (FDA) has agreed that the available efficacy and safety data for Viaskin Peanut supports the submission of a Biologics License Application (BLA) for the treatment of peanut allergy in children four to 11 years of age.
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> The FDA provided written responses to the clinical pre-BLA meeting package submitted by the Company, which reflect agreement on the content of the clinical module of the BLA for Viaskin Peanut. ***DBV remains on track to submit its BLA in the second half of 2018.***
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> "We are pleased with this positive step forward in our progress towards potential approval of Viaskin Peanut, and appreciate the feedback we received from the FDA supporting submission of our BLA," said Dr. Pierre-Henri Benhamou, Chairman & Chief Executive Officer of DBV Technologies. "There are approximately one million children in the U.S. diagnosed with this life-threatening disease, and we look forward to continue working with the agency to address this urgent unmet medical need."

75. The foregoing statement was false and misleading because DBV was not "on track" to submit its BLA at the end of 2018 because, as Defendants were aware, the Company suffered from serious CMC shortcomings and DBV lacked adequate manufacturing procedures and quality controls necessary to support a BLA for FDA approval of Viaskin Peanut.

76. The market responded exuberantly to DBV's long-awaited announcement that the FDA reacted favorably to safety and efficacy of the data as supporting a BLA and agreed to the clinical module of the BLA for the Viaskin Peanut, bringing DBV one step closer to FDA approval of the Viaskin Peanut for

sales in the U.S. After DBV's February 14, 2018 announcement the price of DBV's ADS increased $5.64 per share, a 27% increase from the prior day's closing price. DBV ADS also traded at a whopping *nineteen times* the previous day's volume.

77. Analysts likewise responded by upgrading DBV. For example, on February 14, 2018 JMP Securities LLC ranked DBV "market outperform" setting a price target for DBV of $30.00 (compared to the then-current trading price of $20.86).

78. On February 22, 2018, DBV's Chief Operating Officer boasted of the Viaskin Peanut's CMC readiness and DBV's manufacturing capabilities at the Royal Bank of Canada Healthcare Conference stating, in part:

> *Let's talk about CMC and manufacturing a little bit for a minute. It's also important to understand that DBV Technologies is a company that praises itself for having developed an end-to-end process and a supply chain. So if you take the example, the Viaskin Peanut, we've been able to develop from the peanut itself up to the patch, the final product, all the different processes, manufacturing processes and the new scale developed in order to be able to support the launch of our drug in the U.S. and in other territories.*
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> So what does it mean? Basically, we've developed the manufacturing of an API. The API is a purified, localized extract of peanut developed in our labs and transferred to a CMO that is actually FDA approved. *And we also have developed, which is super specific to DBV, a technology to actually produce these patches.* It's called Electrospray and those machines have been developed by our engineers and have been transferred it to another CMO. ***So we've been able to actually bring everything up to speed in order to scale up*** *our activities and to supply the markets once the product will be,*

hopefully, launched in 2019.

If you actually have the chance to travel to France in the couple of months and if you have to visit the DBV offices, you'll be amazed to see that there are a lot of scientists doing research in our company *but also a lot of engineers really making this into a product*…

We also have developed not only the patch, but also the way to manufacture this patch and the technology that you see here on the left-hand side of the slide is called Electrospray. So basically, we spray the protein or the peptide that we need on through an electric field of 20,000 volts through a very specific process, that actually, I don't know of any kind of process in the pharma industry today. It's a very, very unique to our patch and to the way we manufacture it. This is actually the reason why we have a very nice balance within DBV research and also development.

We are really ready in—we're getting ready on the CMC side. We had a positive interaction with the FDA that helps us contemplate with the filing of our drug by the end of the year, and we are ready to launch that drug.

79. The foregoing statement was false and misleading because DBV was not "ready to launch" Viaskin Peanut, and the Company had not "been able to actually bring everything up to speed" for manufacturing Viaskin Peanut. To the contrary, Defendants were aware the Company suffered from serious CMC shortcomings and DBV lacked adequate manufacturing procedures and quality controls to support a BLA for FDA approval of Viaskin Peanut.

80. On February 23, 2018, DBV published a slide deck in connection with the RBC Capital healthcare conference representing that it had a "Fully scalable, ***launch-ready manufacturing capabilities in place for Viaskin***

Peanut…key commercial roles recruited and onboarded in Summit, New Jersey office."

81. The foregoing statement was false and misleading because DBV's manufacturing capabilities for Viaskin Peanut, in fact, were not "launch-ready." To the contrary, Defendants knew that DBV lacked sufficient manufacturing procedures and quality controls to support a BLA for FDA approval of Viaskin Peanut.

82. In its 2017 20-F, filed on March 16, 2018, DBV described the manufacturing technology for the Viaskin patch, misleadingly representing that it was in compliance with cGMP requirements, stating: "We have engineered a proprietary manufacturing technology for Viaskin patch, which is designed to comply with the most stringent pharmaceutical production standards, including those promulgated by the FDA, in order to enable Viaskin to deliver proteins via intact skin. This novel pharmaceutical process, which was fully developed by us, uses an electrospray to spray homogeneous, thin, dry protein layers onto the Viaskin patch…We believe this patentable technology is highly scalable and complies with cGMP requirements."

83. The foregoing statement was false and misleading because DBV's manufacturing process, in fact, was not "fully developed" and was not then in compliance with cGMP requirements. To the contrary, Defendants knew that

DBV lacked adequate manufacturing procedures and quality controls to support a BLA for FDA approval of Viaskin Peanut.

84. At a March 14, 2018 Barclay's Global Healthcare Conference DBV's Chief Business Officer Susanna Mesa boasted of the Company's in-house machine and the Viaskin Peanut's "heavy technological components," assuring investors that from a CMC standpoint, DBV was on track in terms of receiving clinical approval. Mesa stated:

> Yeah. So just as you know, we announced recently that we had our pre-BLA meeting with the FDA in which we aligned with the agency in terms of the content and the format for our filings for Viaskin Peanut. The content itself is being worked on right now, *so we do have our clinical team working through the clinical modules that will be submitted with the file. But we also, as you know, are a very unique product. It's a very unique product because it's a unique immunotherapy, but it also has a very heavy technological components to it, right?* It's an electrostatic patch. *We have our own machine in-house that we've developed in order to not only formulate the antigen that goes in to the patch, but you spray it in a very unique manner, which is what allows Viaskin to deliver the antigen in the skin and not through the bloodstream.*
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> So we also have, *aside from the clinical standpoint, some CMC requirements that need to be filed with the BLA filing as well.* ***So all of those items will be ready in the second half this year, and that keeps us on track in terms of when we expect to get clinical approval*** and if the products is approved and when we would launch if the product is indeed approved.

85. The foregoing statement was false and misleading because the CMC items were not "on track" for purposes of maintaining BLA and, ultimately, clinical approval timing. To the contrary, Defendants knew the Company suffered

from serious CMC shortcomings and DBV lacked adequate manufacturing procedures and quality controls to support a BLA for FDA approval of Viaskin Peanut.

C. DBV Conducts a Public Offering in March 2018, Selling its Shares at Prices Artificially Inflated by DBV's False and Misleading Statements Concerning its BLA

86. On March 23, 2018, shortly after issuing false and misleading statements assuring investors that from a CMC standpoint, DBV was on track in terms of submitting the BLA and receiving clinical approval which artificially inflated the price of DBV's ADS, the Company announced the closing of its underwritten offering (the "Offering"). In connection with the Offering DBV sold an aggregate of 3,527,752 ordinary shares in (i) a public offering of 1,392,015 ordinary shares in the form of 2,784,030 ADS, in the United States, Canada and certain other countries outside Europe at a public offering price of $21.26 per ADS (on the basis of an exchange rate of $1.2246=€1.00) and (ii) a concurrent private placement of 2,135,737 ordinary shares in Europe (including France) at a public offering price of €34.71 per ordinary share.

87. In addition, the Company announced that the underwriters for the global offering exercised in full their option to purchase an additional (i) 320,360 ordinary shares and (ii) 417,604 ADSs, on the same terms and conditions,

bringing the anticipated total gross proceeds from the global offering to approximately *$172.5 million*.

D. After Raising $172.5 Million From Investors, Defendants Continued to Misleadingly Assure Investors that DBV was on Track to File the BLA and Launch Viaskin Peanut

88. On June 13, 2018, at the Goldman Sachs Global Healthcare Conference, DBV acknowledged the importance of the manufacturing process, assuring investors that DBV was prepared to launch the Viaskin Peanut in 2019 based on its work "scaling up" and "refin[ing] our manufacturing process." Chief Business Officer Susanna Mesa stated:

> As I mentioned at the beginning, we have a technology that we've developed in-house, is engineering heavy and what we've done over the last year is actually prepared to be able to launch our product in 2019, Viaskin Peanut. So we've been doing a lot of work scaling up our JMP manufacturing process. *We actually refined our manufacturing process by integrating an API, the electrospray, which is the machine that's created to manufacture the patch, and what we have at the end is a commercial ready patch called Viaskin Peanut as of today. We do have one machine that's been transferred to our CMO and that will be the commercial operation machine, and we do have plans to start another machine post launch of Viaskin Peanut in 2019.*
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> Most importantly, we have our electrospray machines, which are highly modular and allows us to build a broad platform. *And at the core of the innovation of the electrospray machines, we have a unique engineering capabilities that allow us to really develop this patches or this treatment with a lot of those flexibility, with high replicability, with homogenous repartition of the API's, making it very easy for us to make those very scalable in a commercial setting.*

89. The foregoing statements were false and misleading because Defendants touted their technologies underlying the manufacturing process needed for approval of the BLA, but omitted material information that those manufacturing processes were not fully developed and reliable. In fact, Defendants knew DBV suffered from serious CMC shortcomings and lacked sufficient manufacturing procedures and quality controls to support a BLA for Viaskin Peanut.

90. Then, on September 13, 2018 at the Morgan Stanley Global Healthcare Conference, DBV responded to specific questions related to CMC readiness, pointedly—and misleadingly—assuring investors that DBV had appropriate quantities to launch the Viaskin Peanut and that the Company was well-positioned for filing a BLA from a CMC perspective:

> Q: But maybe just remind us on manufacturing, where you are with that. How many doses can you produce? How much of the market you think you can supply at launch and any sort of CMC issues, FDA inspection issues, et cetera, that we should consider.
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> Trapp: Yeah. So, I'll start and Susanna can augment. So, I've actually got- had a chance to go over to France and see the manufacturing process. It's really, really cool and innovative. You spray 250 micrograms into a patch with an electrostatic process. So, it gets on the patch. *And so, a very elegant process, one we've spent a lot of time continuing to perfect and scale up. We do have appropriate quantities for launch available with where we are today. The capacity of each machine is about 30 million patches. So, we believe that's enough to get us through launch and we're continuing to look at other plans for it we need a second machine, how we bring that on.* Maybe I'll ask Susanna to comment on any BLA or other.

> Mesa: Yeah. I think the major hurdles from a CMC standpoint which was really the technology transfer for our commercial CMO.[4] We transferred machine back in April 2017 on time where it allowed us to finalize a technology transfer that we need get done before launch. So, I think from that standpoint, we feel pretty comfortable where we are. There was a key component that I think for us it was very important and it was making sure the FDA was going to be okay with our filing strategy. *We will be filing with two stability batches of about six months and one stability batch of three months, and they were comfortable with that approach and we confirm that in our CMC pre-BLA meetings. So, I think, overall, all of those key challenges that were important for DVB, we've tackled on. We have a really great CMC team and I think they've done a really nice job of positioning us for success as we are approaching filing.*

91. The foregoing statement was false and misleading because Defendants touted their technologies underlying the manufacturing process needed for approval of the BLA, but omitted material information that those manufacturing processes were not fully developed, and did not meet FDA requirements and were reliable. In fact, DBV suffered from serious CMC

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[4] A contract manufacturing organization (CMO), sometimes called a contract development and manufacturing organization (CDMO), is a company that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services from drug development through drug manufacturing. This allows major pharmaceutical companies to outsource those aspects of the business, which can help with scalability or can allow the major company to focus on drug discovery and drug marketing instead. Services offered by CMOs include, but are not limited to: pre-formulation, formulation development, stability studies, method development, pre-clinical and Phase I clinical trial materials, late-stage clinical trial materials, formal stability, scale-up, registration batches and commercial production. CMOs are contract manufacturers, but they can also be more than that because of the development aspect. Their customers are not only expecting competitive pricing but also regulatory compliance, flexibility on the production capability and on time delivery. Overall it is required that CMO complies with good manufacturing practice from their client and official organization such as Food and Drug Administration.
https://en.wikipedia.org/wiki/Contract_manufacturing_organization

shortcomings and lacked sufficient manufacturing procedures and quality controls to support a BLA for FDA approval of Viaskin Peanut.

92. As the time for DBV to submit its BLA drew closer, DBV continued to tout its manufacturing process, assuring investors that it was able to comply with CMC by insuring product consistency. At the October 2, 2018 Cantor Global Healthcare Conference an analyst asked:

> Q: And then from a manufacturing perspective, obviously, you've had this on pre-BLA meeting with the FDA. What did they ask for from a manufacturing standpoint? *And if you would give us some of the history of how you manufacture these patches and what give you confidence that you're giving- every patch is the exact same patch?*
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> Susanna Mesa responded:
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> Yeah. So, that's actually been one of the uniqueness of DBV and one that we don't talk too much about is manufacturing. And the reason that's an exciting area for us is because we actually develop our own machine. They're the electrospray machines designed by actually another one of our co-founders, Bertrand Dupont, who wanted to find a way to ensure dose replicability and does stability over time in patches. And so we came out with this new technology that's been used in the semiconductor space before, it's called the electrospray. And basically what it does is it takes on liquid formulation of an antigen. In the case of peanut, a peanut antigen is sprays to dry [indiscernible] of the patch. *And because it's highly technicalized, then it's actually pretty replicable. And we can choose in terms of how many patches we want to produce because each electrospray is just one knuckle. And as long as you can control one knuckle, you can control the other knuckle.*
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> *So we've worked on that technology for 15 years.* We're currently in our GEN4.0 machine, which is in our CMO today and [ph] for REVA in France. And from a manufacturing standpoint, the requirements of the FDA has asked are pretty much along the same line of what

> they've asked for their patch development. Some adhesion testing, some stability testing.
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> So the FDA did request three batches with stability data from the different patches *And today, one of the things that we've agreed on, on the FDA and it was one of the major, I would say, components of the file was actually the stability data*. And two of them are actually going to be at six months and then one of them at three months. It is usually customary that the three of them are all at six months, but it's something that we agreed with on the FDA during our pre-BLA meeting and we agreed to that three-month and two six-month batches.
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> *So from the manufacturing standpoint, I think we're there*. Obviously, one of the key focus for DBV and one of the important things that we have to focus on and continue hiring talent is manufacturing, right, to ensure that there's everything that we need to do by the time we launch the product is done and to make sure that we're inception ready, that we're working with the FDA to help them understand the electrospray to making sure that we have all of our I's dotted and our t's crossed that that at we're heading in to the approval process, *this is something that can be highly automatized and it's something that we can show the FDA that hopefully we have everything under control here.*

93. The foregoing statement was false and misleading because Defendants assured investors that "*from the manufacturing standpoint*" DBV was on track with its BLA and assured investors "we're there," when Defendants knew that its manufacturing processes and quality controls did not meet FDA requirements. Defendants omitted material information that its manufacturing processes actually were not fully developed and reliable. In fact, DBV suffered from serious CMC shortcomings and lacked sufficient manufacturing procedures and quality controls to support a BLA for FDA approval of Viaskin Peanut.

E. DBV Technologies Announces Submission of Biologics License Application for Viaskin Peanut to the U.S. Food and Drug Administration

94. On October 22, 2018, DBV announced it had submitted a BLA to the FDA for Viaskin Peanut for the treatment of peanut allergy in children four to 11 years of age. DBV's press release stated, in relevant part:

> DBV Technologies (Euronext: DB - ISIN: FR0010417345 - Nasdaq Stock Market: DBVT) today announced the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for Viaskin Peanut for the treatment of peanut allergy in children four to 11 years of age. Viaskin Peanut is the Company's lead product candidate, which is based on epicutaneous immunotherapy (EPIT), a proprietary technology platform that delivers biologically active compounds to the immune system through the skin.
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> "This submission represents a significant step forward for those families living with peanut allergy. We are thankful for the patients, investigators and DBV employees' efforts in making this milestone possible," said Dr. Pierre-Henri Benhamou, Chairman & Chief Executive Officer of DBV Technologies. "We have been developing Viaskin Peanut for over 10 years, with over 1,000 patients studied in our clinical trials, and we are excited about the possibility of helping patients suffering from peanut allergy."
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> Viaskin Peanut previously received Breakthrough and Fast Track Designation from the FDA in 2015 and 2012, respectively. The BLA for Viaskin Peanut is supported by a global development program comprised of seven clinical trials. Data from Phase III studies, PEPITES and REALISE, which studied patients four to 11 years of age for 12 months, as well as supportive long-term data from the Company's open-label Phase II program, were included in this submission.
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> Dr. Hugh Sampson, Chief Scientific Officer of DBV Technologies and Kurt Hirschhorn Professor of Pediatrics at the Icahn School of

> Medicine at Mount Sinai said, "We believe that the safety and efficacy data generated in our clinical trials support our mission to potentially offer EPIT, a proprietary desensitization treatment, to peanut-allergic children in an easy and convenient manner for families."

95. It was misleading for the Company to announce the submission of the BLA and optimistic sentiment for FDA approval when Defendants were aware that DBV's manufacturing processes and quality control were inadequate to support FDA approval. Defendants misleadingly omitted material information that its manufacturing processes actually were not fully developed and reliable. In fact, DBV suffered from serious CMC shortcomings and lacked sufficient manufacturing procedures and quality controls to support a BLA for Viaskin Peanut.

F. DBV Suddenly Withdraws its BLA, Causing the Price of DBV ADS to Plummet

96. On December 19, 2018, after the close of trading, the Company issued a press release announcing that its "BLA [for Viaskin Peanut was] withdrawn following discussions with FDA regarding insufficient data on manufacturing procedures and quality controls[.]" The press release stated, in relevant part:

> DBV Technologies Provides Update on Viaskin Peanut for Children Four to 11 Years of Age
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> BLA withdrawn following discussions with FDA regarding insufficient data on manufacturing procedures and quality controls

> DBV to work with the agency to pursue resubmission as quickly as possible
>
> The FDA did not cite concerns related to the safety or efficacy of Viaskin Peanut in the BLA
>
> *DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT) today announced that after discussions with the U.S. Food and Drug Administration (FDA), its Biologics License Application (BLA) for Viaskin Peanut in children four to 11 years of age has been voluntarily withdrawn.* DBV is currently working closely with the agency to resubmit the application for Viaskin Peanut as quickly as possible.
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> This action was based on verbal and written correspondence with the FDA on December 18th, 2018. *Following feedback from the agency, DBV Technologies concluded that the current BLA, which was submitted on October 18th, 2018, lacks sufficient detail regarding data on manufacturing procedures and quality controls.* The FDA did not cite concerns related to the clinical module of the BLA for Viaskin Peanut, and the Company believes that the additional information needed to support this filing is available without further clinical studies.
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> *"Although the agency did not reference any medical or clinical questions with the submission of Viaskin Peanut, the FDA did communicate that the level of detail with regards to data on manufacturing and quality controls was insufficient in the BLA,"* said Daniel Tassé, Chief Executive Officer of DBV Technologies. "We remain confident in the clinical profile of Viaskin Peanut and its potential to offer treatment to peanut-allergic children. Our plan is to address these concerns as quickly as possible and to work closely with the FDA to provide an updated and complete file."

97. On this news, shares of DBV Technologies fell $8.39 per share or nearly 60% to close at $5.76 per share on December 20, 2018, damaging investors.

98. DBV's bad news was good news for its rival, Aimmune Therapeutics, Inc., whose share price rose $3.76 per share on December 20, or 15% from its December 19 closing price, trading at 4.75 times its December 19 volume.[5]

99. Also on December 19, 2018, DBV hosted a conference call discussing its withdrawal of its BLA for Viaskin Peanut. The call was hosted by Daniel Tassé, DBV's new CEO. On November 16, 2018, just one month before announcing its decision to withdraw the BLA for the Viaskin Peanut, DBV announced that effective November 29, 2018 Defendant Benhamou would no longer serve as CEO and that Daniel Tassé would takeover as CEO as of that date.

100. Tassé fielded analysts' questions about the CMC issues and FDA feedback that led DBV to suddenly withdraw the BLA. Tassé explained:

> These are CMC issues that often happen in this process and I've seen that before. I obviously wish to spend a lot of time to understand them fully, we've had our first read from the team already on the nature of them. And I want to make sure I come back to all of you with a clear view of what will be the time required to address them. But these seem to be questions that can be addressed. In due time, I'd be happy to come back and provide that clarity. But at this point in time, we need some latitude to go and understand it fully, and come back with the clarity that our patients deserve and the marketplace deserves.
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> As far as your question, a bit more color on the comments from the

[5] On September 13, 2019 an FDA Advisory Committee endorsed the effectiveness of Aimmune's peanut allergy treatment, known as AR101 and voted to endorse a safety plan the FDA proposed to support the treatment's use in children and teenagers.

> FDA. They are, as we described in the press release, complements of information, precision on data, precision on analyses, SOPs, things that are again quite common as part of the BLA CMC process. And questions, again, we're very grateful for the FDA yesterday taking the time to reach out to us, have a dialogue, give us a heads up to it, so that we can assess where we are and very constructively make the decision that we've announced today.
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> The review came at the end of the 60-day process and on the phone was the representation from all of the FDA. *The questions they had for us and be able to reach to us was all to do with CMC*. So, there was no questions, no comments made about Section 2 or about the safety, efficacy and the clinical profile of the product.
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> . . .

Analysts pressed on whether the CMC issues had to do with specific formulation issues related to the Viaskin Peanut patch, to which Tassé evaded response—citing his freshman status at the Company:

> JASON ERON ZEMANSKY [of Barclays]: Just to follow up on a number of comments. ***Is the CMC questions, were they specific to the formulation that, that of patch aspect to it?*** And then, kind of to follow up, given the FDA's previous review, what should we think about in terms of the resubmission? Is there any possibility that FDA will kind of bypass some of the scientific and clinical efficacy questions to focus more on the CMC issues? Or is it going to be a complete and total review of the entire package.
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> TASSE: Yes. I don't wish to speculate on how the FDA will approval the review here. We would expect this being, obviously, Breakthrough Therapy where the clinical profile is important that the FDA will be reviewing, obviously, the whole file.
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> . . .
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> And again, I want to be very clear. I want – I'm new.

Analysts drilled down on the timing of when Defendants learned of the FDA's concerns with the BLA:

> TAZEEN AHMAD [of BOFA Merrill Lynch]: …can you give us a sense of when discussions with the FDA regarding specifically manufacturing started, because obviously with the breakthrough status that would mean that the company would have had multiple opportunities, I think, to communicate with the agency either in writing or in person or on the phone. Was this something that was brought up recently in your discussions or can you just give us a timeline of when this popped up?
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> TASSE: Yeah. The FDA reached out to us on Monday to say- I'm sorry, on Tuesday, yesterday- to say that we have a number of observations we'd like to share with you. They were again, as I say, very constructive in doing it and giving us heads up, a chance to think through how we want to handle it. We chose to withdraw the file, so that we can address those concerns of theirs in a way that it- we've all the latitude to do it obviously and do it the right way, both those discussions actually emerged in the last day.
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> AHMAD: In terms of what other options they gave you besides the option to withdraw, can you give us some color on that?
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> TASSE: Yeah. The other option was to continue with the file, quite simply, but the right decision here was for us to withdraw the file. With the feedback that was provided by the agency, again, it was very constructive, so that we have great clarity on the questions the agency wants us to address. And with that great clarity and that collegial approach, we chose to pull the file, to withdraw it, and carefully and precisely asses the best way to respond to those questions here.
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> AHMAD: …[D]o you think that this will be simply addressing the questions about manufacturing and moving on as planned with the BLA?
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> TASSE: Well, you're asking me to speculate on what the agency will do once we resubmit here. *We do know that what they've asked to discuss with us and what they express has been the areas they want us*

to focus on, all had to do with CMC and manufacturing.

In response to whether the Company was in a position to arrange a formal meeting with the FDA, Tassé suggested that the Company first needed to marshal additional resources and hire FDA experts in order to address the CMC issues:

> TASSE: We will bring in outside expertise, people who are experts in these areas and also have worked with the FDA in the past, so that we can decide whether or not a dialogue with the agency is indicated as part of our response here. That's something I believe the agency would be very much amenable to do, but that decision has not been made at this point in time.
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> JOSEPH PATRICK SCHWARTZ [of Leerink]: …So, I think you said that you believe the information that you need to support the filing is available without further clinical studies, but then you also want to take some time to understand it as well and you can to address it with great precision. So, I'm just wondering how strongly do you think that you understand what the FDA has issues with and how strongly do you think you can address the FDA's issues without having to do, for example, additional manufacturing campaigns? Have you been capturing the types of information on the product and how it's produced in terms of specs and things in order to address the issues that the FDA is raising now?
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> TASSE: Yeah. The dataset, the data capture we have I think is one that I need to query and understand fully here. We have to be honest with each and other in a situation right now that was, obviously, not one that we were expecting here.
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> SCHWARTZ: …Did the FDA say that you would receive a RTF if you did not withdraw the application? I'm just wondering why this can't be resolved in the normal course of the review and if this implies that it will take more time than that, the withdrawal of the BLA?
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> TASSE: Yeah. The withdrawal of the BLA allows us to do all of this in a time that we control and that struck me as maybe the best option.

When asked when the Company became aware of the CMC deficiencies in the BLA for the Viaskin Peanut, Tassé deflected, emphasizing that he had only worked at the Company for three weeks:

> LIISA ANN BAYKO [of JMP]: *Did you have any sense before that the application was deficient on any of these components*? ….
>
> TASSE: *Any sense from the agency? No.*
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> BAYKO: No, *Just on your own, kind of, review*.
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> TASSE: *I've been here for three weeks*…I'm still very much in the diligence mode….So I wish I could give you a more complete answer.

Tassé confirmed that the FDA's feedback, and DBV's decision to withdraw the BLA, related to not only one particular deficiency but "many elements of CMC:"

> MATTHEW KELSEY HARRISON [of Morgan Stanley]: . . .can you just maybe comment on the scope of the questions, did it cover broadly all areas of CMC or was it focused on a certain area, say, documentation or release assay validation or something like that?
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> TASSE: Yeah, *so it touches many elements of CMC*, but all the observations were rather precise. So, these were very, very specific observations that did not go to all of systems, *but it went to specific observations, specific questions the agency had around our processes here*. So, they were not, what I would say, comments on the overall system or overall SOPs, but quite precise questions here that again are – what I've seen in my experience, exactly the type of questions that you'd get from the agency in a review here…..precise questions that touch many elements of our manufacturing process.

Tassé further responded to analysts questions concerning how DBV produced the product in a cGMP manner and doubled-down on the Company's ability to reproduce consistent dosage of Viaskin Peanut:

> SCHWARTZ: So obviously, you don't have any approved products, which are coming out of your manufacturing facilities and then electrospray technologies is advanced -- impressive, ***but can you tell us how you've designed this in order to produce product in [cGMP] manner? I'm just wondering about things like the consistency of dosage that's on each patch***, shelf stability at different temperatures and things like that. I mean, have you had an opportunity to think about the basic list of things that you would expect the FDA would want to scrutinize like dosing and stability. Anything else...

In response, Defendant Tassé reassured investors as to the state of manufacturing:

> TASSE: So I've spent a good chunk of last week for the manufacturing people in Bagneux. And I have said, I was quite impressed by the technology, the cleverness of it. ***And I'm comfortable -- very comfortable that our ability to, essentially, manufacturing the patch and deliver 250 micrograms with great consistency from one patch to the other is something that the team has very much achieved***.
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> . . .
>
> ***But I -- the core technology, the ability to make a patch is something that I think is very solid and our ability to do that in a way that is consistent is something that I was impressed when I saw the facility in Bagneux last week.***

101. Tassé's statements concerning DBV's sudden withdrawal of the BLA for the Viaskin Peanut was false and misleading because Defendants had known throughout the Class Period that DBV's manufacturing processes actually were not fully developed and reliable. In fact, DBV suffered from serious CMC shortcomings and lacked sufficient manufacturing procedures and quality controls to support a BLA for FDA approval of Viaskin Peanut.

VI. ADDITIONAL ALLEGATIONS REGARDING DEFENDANTS' SCIENTER

102. During the Class Period, DBV had no approved drugs and generated no significant income from operating activities. Viaskin Peanut, which the Company had spent 10 years developing and which had just recently before the Class Period completed a Phase 3 study that demonstrated efficacy, was thus a critical product candidate and the focus of significant attention by the Company. By Defendants' own admissions, the CMC for Viaskin Peanut and developing and maintaining manufacturing processes that were cGMP compliant was an important focus of the Company during the Class Period, supporting a strong inference of scienter.

103. The suspicious timing of DBV's announcement of its withdrawal of the BLA also supports a strong inference of scienter. As explained above, from the time a marketing application is submitted, the FDA has 60 days to perform an initial review. During this time FDA will determine if the submission is sufficiently complete to accept the application for filing and thereafter perform a more substantive review. Because the purpose of this initial 60-day review period is to allow the FDA to identify and communicate application deficiencies to the applicant, and to allow the applicant to cure them, the FDA typically communicates such problems to an applicant as early during the review period as possible. This supports a strong inference that Defendants were aware of the

CMC problems identified by the FDA prior to announcing the BLA withdrawal on December 19, 2019—a mere two days before the FDA's filing decision was due.

104. The suspicious timing of the resignation of DBV's CEO, Pierre-Henri Benhamou, during the Class Period further supports scienter. On November 29, 2018, just over a month after the BLA was submitted and just three weeks before DBV's announcement that it was withdrawing the BLA for the Viaskin Peanut, DBV co-founder Pierre-Henri Benhamou stepped down as CEO.

105. Then, on January 3, 2019, two weeks after DBV withdrew its BLA, DBV announced that that its Chief Medical Officer Dr. Lucia Septien-Velez was leaving the Company to "pursue other opportunities." Hugh Sampson would assume the role of CMO.

106. Furthermore, on March 5, 2019, DBV announced that Pierre-Henri Benhamou had resigned from the Board of Directors. On November 29, 2018, Benhamou stepped down from his post as CEO, but remained on the Board of Directors until March 5, 2019. Again, the Company's press release stated that "Dr. Benhamou did not express any disagreement with the Company on any matter relating to the Company's operations, policies or practices," but provided no reason for his departure.

VII. CORPORATE SCIENTER

165. During the Class Period, Defendants Tassé, Benhamou, Schilansky and Mesa served as CEO and CFO, Principal Financial Officer and CBO, respectively. As CEO and CFO, Tassé, Benhamou and Schilansky signed Class Period SEC filings on behalf of DBV. Defendant Tassé signed DBV's 2018 20-F filed with the SEC on April 1, 2019. Defendant Benhamou signed the Company's 2017 20-F filed with the SEC on March 16, 2018. Defendant Schilansky signed the Company's 2017 20-F and 2018 20-F filed with the SEC on March 16, 2018 and April 1, 2019, respectively. Defendants Tassé, Benhamou and Schilansky therefore, acted with apparent authority to speak on behalf of the Company and their statements were made with the imprimatur of the Company that selected them to speak on its behalf. Moreover, as CEO, CFO, Principal Financial Officer and Chief Business Officer, Defendants were highly involved in the preparation, review, finalization, and issuance of the Company's statements, and investors relied on their honesty and integrity.

166. Based on the foregoing, Defendant Tassé's, Benhamou's, Schilansky's and Mesa's actions and scienter are imputable to DBV at all times during the Class Period. Defendants Tassé, Benhamou, Schilansky and Mesa acted as an agent of DBV, both with respect to the SEC filings that they signed and also with respect to the SEC filings, press releases and conference calls that they

assisted in preparing and/or that they oversaw or participated in. Therefore, Defendants Tassé's, Benhamou's, Schilansky's and Mesa's state of mind is imputable to DBV for all of the challenged statements in this Complaint, whether or not they personally signed those statements.

VIII. APPLICABILITY OF PRESUMPTION OF RELIANCE

A. Fraud-on-the-Market Doctrine

107. Investors are entitled to rely, and will rely, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

b. the omissions and misrepresentations were material;

c. DBV ADS are traded in an efficient market;

d. the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of DBV's ADS; and

e. Investors and members of the Class purchased, acquired and/or sold DBV ADS between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

108. At all relevant times, the market for DBV ADS was an efficient market for the following reasons, among others:

- DBV's ADS met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient and automated market;

- During the Class Period, the average weekly trading volume for DBV ADS on the NASDAQ was 894,217 shares, which represents approximately 1.52% of DBV's outstanding ADS during the Class Period permitting a strong presumption of reliance;

- At least 9 stock market analysts followed DBV and wrote a total of at least 44 reports on DBV during the Class Period. Analysts covering DBV included: Stifel Nicolaus; SVB Leerink; Barclays; Jefferies; JMP Securities LLC; Morgan Stanley; Kempen & Co; H.C. Wainwright & Co. and; Deutsche Bank;

- DBV regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

- More than 25 member firms were active market-makers in DBV ADS at all times during the Class Period;

- During the Class Period DBV was eligible for S-3 registration;

- DBV's market capitalization exceeded $840 million on all days during the Class Period.

- Unexpected material news about DBV was rapidly reflected and incorporated into the Company's stock price during the Class Period.

109. As a result of the foregoing, the market for DBV promptly digested current information regarding DBV from all publicly available sources and reflected such information in DBV's stock price. Under these circumstances, all purchasers of DBV ADS during the Class Period suffered similar injury through their purchase of DBV ADS at artificially inflated prices, and a presumption of reliance applies.

B. Affiliated Ute

110. Neither Investors nor the Class need prove reliance – either individually or as a class – because under the circumstances of this case, positive proof of reliance is not a prerequisite to recovery, pursuant to ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security.

IX. INVESTORS' CLASS ACTION ALLEGATIONS

111. Investors bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all persons other than defendants who acquired DBV Technologies ADS traded on NASDAQ during the Class Period, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of DBV Technologies,

members of the Individual Defendants' immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

112. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, DBV Technologies ADS were actively traded on the NASDAQ. While the exact number of Class members is unknown to Investors at this time and can be ascertained only through appropriate discovery, Investors believe that there are hundreds, if not thousands of members in the proposed Class.

113. Investors' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

114. Investors will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Investors have no interests antagonistic to or in conflict with those of the Class.

115. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the Exchange Act were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the financial condition and business DBV Technologies;
- whether Defendants' public statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
- whether Defendants caused DBV Technologies to issue false and misleading SEC filings during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and SEC filing
- whether the prices of DBV Technologies' securities during the Class Period were artificially inflated because of Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

116. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is

impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

117. Investors will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- DBV Technologies shares met the requirements for listing, and were listed and actively traded NASDAQ, a highly efficient and automated market;
- As a public issuer, DBV Technologies filed periodic public reports with the SEC;
- DBV Technologies regularly communicated with public investors via established market communication mechanisms, including through the regular dissemination of press releases via major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

- DBV Technologies was followed by a number of securities analysts employed by major brokerage firms who wrote reports that were widely distributed and publicly available.

118. Based on the foregoing, the market for DBV Technologies securities promptly digested current information regarding DBV Technologies from all publicly available sources and reflected such information in the prices of the shares, and Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

119. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information as detailed above.

X. CLAIMS FOR RELIEF

COUNT I
For Violations of Section 10(b) And Rule 10b-5 Promulgated Thereunder Against All Defendants

120. Investors repeat and reallege each and every allegation contained above as if fully set forth herein.

121. This Count is asserted against Defendants is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

122. During the Class Period, Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

123. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

- employed devices, schemes and artifices to defraud;
- made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or
- engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of DBV Technologies securities during the Class Period.

124. Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of DBV Technologies were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated, or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These defendants by virtue of their receipt of information reflecting the true facts of DBV Technologies, their control over, and/or receipt and/or modification of DBV Technologies' allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning DBV Technologies, participated in the fraudulent scheme alleged herein.

125. Individual Defendants, who are the senior officers and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Investors and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other DBV Technologies personnel to members of the investing public, including Plaintiff and the Class.

126. As a result of the foregoing, the market price of DBV Technologies securities was artificially inflated during the Class Period. In ignorance of the falsity of Defendants' statements, Investors and the other members of the Class relied on the statements described above and/or the integrity of the market price of DBV Technologies securities during the Class Period in purchasing DBV Technologies securities at prices that were artificially inflated as a result of Defendants' false and misleading statements.

127. Had Investors and the other members of the Class been aware that the market price of DBV Technologies securities had been artificially and falsely inflated by Defendants' misleading statements and by the material adverse information which Defendants did not disclose, they would not have purchased DBV Technologies securities at the artificially inflated prices that they did, or at all.

128. As a result of the wrongful conduct alleged herein, Investors and other members of the Class have suffered damages in an amount to be established at trial.

129. By reason of the foregoing, Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the plaintiff and the other members of the Class for substantial damages which they

suffered in connection with their purchase of DBV Technologies securities during the Class Period.

COUNT II
Violations of Section 20(a) of the Exchange Act
Against the Individual Defendants

130. Investors repeat and reallege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

131. During the Class Period, the Individual Defendants participated in the operation and management of DBV Technologies, and conducted and participated, directly and indirectly, in the conduct of DBV Technologies' business affairs. Because of their senior positions, they knew the adverse non-public information about DBV Technologies' misstatement of revenue and profit and false financial statements.

132. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to DBV Technologies' financial condition and results of operations, and to correct promptly any public statements issued by DBV Technologies which had become materially false or misleading.

133. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which DBV Technologies disseminated

in the marketplace during the Class Period concerning DBV Technologies' results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause DBV Technologies to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of DBV Technologies within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of DBV Technologies securities.

134. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by DBV Technologies.

XI. PRAYER FOR RELIEF

WHEREFORE, Investors, on behalf of themselves and the Class, prays for judgment and relief as follows:

(a) declaring this action to be a proper class action, designating plaintiffs as Lead Plaintiffs and certifying Plaintiffs as class representatives under Rule 23 of the Federal Rules of Civil Procedure and designating Plaintiffs' counsel as Lead Counsel;

(b) awarding damages in favor of Investors and the other Class members against all defendants, jointly and severally, together with interest thereon;

(c) awarding Investors and the Class reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) awarding Investors and other members of the Class such other and further relief as the Court may deem just and proper.

XII. JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

Dated: January 24, 2020

Respectfully submitted,

THE ROSEN LAW FIRM, P.A.

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Co-Lead Counsel for Lead Plaintiffs and the Putative Class

PROOF OF SERVICE

I, the undersigned say:

I am not a party to the above case and am over eighteen years old.

On January 24, 2020, I served true and correct copies of the foregoing document, by posting the document electronically to the ECF website of the United States District Court for the District of New Jersey, for receipt electronically by the parties listed on the Court's Service List.

I affirm under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on January 24, 2020.

s/ Laurence M. Rosen
Laurence M. Rosen